



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 2, 2016

Exactech®, Incorporated
Mr. Graham L. Cuthbert
Regulatory Affairs Specialist II
2320 N.W. 66th Court
Gainesville, Florida 32653

Re: K121067

Trade/Device Name: Exactech® Equinoxe® Shoulder System Short Replicator Plates
Regulation Number: 21 CFR 888.3660
Regulation Name: Shoulder joint metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: PHX, KWT, KWS, HSD
Dated: October 31, 2012
Received: November 6, 2012

Dear Mr. Cuthbert:

This letter corrects our substantially equivalent letter of December 6, 2012.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Lori A. Wiggins -S

for

Mark N. Melkerson

Director

Division of Orthopedic Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Exactech® Equinoxe® Shoulder System Short Replicator Plates
Special 510(k) – Indications for Use

Indications for Use Statement

510(k) Number:

K121067

Device Name: Exactech® Equinoxe® Shoulder System Short Replicator Plate

INDICATIONS FOR USE

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
✓	✓		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative problems
✓	✓		Congenital abnormalities in the skeletally mature
✓			Primary and secondary necrosis of the humeral head.
✓		✓	Humeral head fracture with displacement of the tuberosities
✓	✓		Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
✓	✓		Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
		✓	Displaced three-part and four-part upper humeral fractures

Exactech® Equinoxe® Shoulder System Short Replicator Plates
Special 510(k) – Indications for Use

	✓	Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
	✓	Revision of failed previous reconstructions when distal anchorage is required
✓	✓	To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

Prescription Use X

(Part 21 CFR 801 Subpart D)

and/or

Over-The-Counter Use _____

(21 CFR 807 Subpart C)

Please do not write below this line – use another page if needed.

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Krishna Asundi
 (Division Sign-Off)
 Division of Orthopedic Devices

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K121067(1/4)

**Exactech® Equinoxe® Shoulder System Replicator Plates
Special 510(k) – 510(k) Summary of Safety and Effectiveness**

DEC 06 2012

510(k) Summary of Safety and Effectiveness

Sponsor: **Exactech® Inc.**
2320 N.W. 66th Court
Gainesville, FL 32653

Phone: (352) 377-1140
Fax: (352) 378-2617

FDA Establishment Number 1038671

Contact: **Graham L. Cuthbert**
Regulatory Affairs Specialist II

Date: **December 3rd, 2012**

Trade or Proprietary or Model Name(s):

Exactech® Equinoxe® Shoulder System Replicator Plate, Short, 1.5mm offset
Exactech® Equinoxe® Shoulder System Replicator Plate, Short, 4.5mm offset
Exactech® Equinoxe® Shoulder System Fixed Angle Replicator Plate, Short, 0mm offset
Exactech® Equinoxe® Shoulder System Fixed Angle Replicator Plate, Short, 1.5mm offset
Exactech® Equinoxe® Shoulder System Fixed Angle Replicator Plate, Short, 4.5mm offset

Common Name:

Shoulder Prosthesis

Classification Name:

Shoulder joint metal/polymer non-constrained cemented prosthesis
(21 CFR 888.3650, Class II, Product Code KWT)

Shoulder joint metal/polymer semi-constrained cemented prosthesis
(21 CFR Section 888.3660, Product Code KWS)

Shoulder joint humeral (hemi-shoulder) metallic uncemented prosthesis.
(21 CFR Section 888.3690, Product Code HSD)

Exactech® Equinoxe® Shoulder System Replicator Plates
Special 510(k) – 510(k) Summary of Safety and Effectiveness

Information on devices to which Substantial equivalence is claimed:

510(k) Number	Trade or Proprietary or Model Name	Manufacturer
K042021	Equinoxe Shoulder System	Exactech, Inc.
K102951	Equinoxe Fixed Angle Replicator Plates	Exactech, Inc.

Device Description:

This submission proposes modifying the Exactech Equinoxe Replicator Plates and Fixed Angled Replicator Plates cleared under 510(k) #K042021 and #K102951. The proposed modifications are as follows:

1. The proposed replicator plates and the fixed angled replicator plates will attach to the humeral head using a morse taper that is half the height of the morse taper of the anatomic replicator plates and fixed angled replicator plates cleared in 510(k) #K042021 and 510(k) #K102951.

The proposed Exactech Equinoxe Replicator Plates, and Fixed Angled Replicator Plates are intended to be used with the same Equinoxe Shoulder system components described in 510(k). #K042021 and #K102951 as cited predicates.

Intended Use of the Device:

The Equinoxe Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases or fractures of the glenohumeral joint where total or hemi- arthroplasty is determined by the surgeon to be the preferred method of treatment.

- The cemented primary humeral stem, long/revision stem, fracture stems and all Equinoxe glenoids are intended for cemented fixation.
- The press-fit humeral stems are intended for press-fit applications but may be used with bone cement at the discretion the surgeon.
- The reverse humeral components are intended to be used in cemented applications or in revision cases when the humeral component is well-fixed/stable, as deemed by the orthopaedic surgeon.
- Humeral Heads are intended for use in cemented and press-fit applications.

Clinical indications for the PRIMARY (P), LONG/REVISION (L), and FRACTURE (F) humeral components are as follows:

P	L	F	Indications
✓	✓		Rheumatoid arthritis, osteoarthritis, osteonecrosis or post-traumatic degenerative

Exactech® Equinoxe® Shoulder System Replicator Plates
Special 510(k) – 510(k) Summary of Safety and Effectiveness

problems		
✓	✓	Congenital abnormalities in the skeletally mature
✓		Primary and secondary necrosis of the humeral head.
✓	✓	Humeral head fracture with displacement of the tuberosities
✓	✓	Pathologies where arthrodesis or resectional arthroplasty of the humeral head are not acceptable
✓	✓	Revisions of humeral prostheses when other treatments or devices have failed (where adequate fixation can be achieved)
	✓	Displaced three-part and four-part upper humeral fractures
✓		Spiral and other fractures of the mid-humerus (in combination with glenohumeral degenerative diseases)
✓		Revision of failed previous reconstructions when distal anchorage is required
✓	✓	To restore mobility from previous procedures (e.g. previous fusion)

The Equinoxe Reverse Shoulder System is indicated for use in skeletally mature individuals with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff. The Equinoxe Reverse Shoulder is also indicated for a failed glenohumeral joint replacement with loss of rotator cuff function resulting in superior migration of the humeral head.

The Equinoxe Platform Fracture Stem is indicated for use in skeletally mature individuals with acute fracture of the proximal humerus and displacement of the tuberosities, displaced 3- and 4-part fractures of the proximal humerus (hemi-arthroplasty), or acute fracture of the proximal humerus with failure of the glenohumeral joint (primary total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is also indicated for acute fracture of the proximal humerus in combination with degenerative diseases of the glenohumeral joint and a grossly deficient, irreparable rotator cuff resulting in superior migration of the humeral head (reverse total shoulder arthroplasty). The Equinoxe Platform Fracture Stem is indicated for cemented use only.

Rationale for Substantial Equivalence:

Intended Use / Indications for Use - Proposed and predicate devices have identical indications for use.

Materials - Proposed and predicate devices are composed of identical biocompatible materials conforming to recognized industry standards for permanent implants.

Design Features - Proposed and predicate devices have the same key design features, and mate with all existing implant and instruments of the Equinoxe shoulder system.

Dimensions - The proposed replicator plates and fixed angled replicator plates have the same dimensions, same taper geometry, and mate with all existing humeral heads; with the exception of the shortened taper height.

Packaging and Sterilization - Proposed and predicate devices are packaged and sterilized using the same materials and processes.

Device Shelf Life - Proposed and predicate devices have the same shelf life.

**Exactech® Equinoxe® Shoulder System Replicator Plates
Special 510(k) – 510(k) Summary of Safety and Effectiveness**

Summary of Non-Clinical Performance Data:

- Humeral head pull-off to determine taper engagement strength per ASTM F2009-00
- Cadaveric validation to confirm humeral head can be impacted on axis.

Substantial Equivalence Conclusion:

Test and analysis provided in this 510(k) submission demonstrate that the proposed Exactech Equinoxe Shoulder System Replicator Plates and Fixed Angled Replicator Plates are substantially equivalent to the cleared predicate devices.